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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,605	12/09/2003	David James Dooley	PC25026A	4759
28880	7590	06/06/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/731,605	DOOLEY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13-16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 17, 18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>19 September 2005</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### **Claims 1-20 are presented for examination.**

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/433,491, filed December 13, 2002. Applicant's Information Disclosure Statement (IDS) filed September 19, 2005 (two pages total) has been received and entered into the application. As reflected by the attached, completed copy of form PTO/SB/08A, the Examiner has considered the cited references. Applicant's response filed May 8, 2006 to the requirement for election dated March 7, 2006 has also been received and entered into the present application.

#### ***Requirement for Election***

Applicant was required under 35 U.S.C. 121 to elect a single disclosed species of disorder or condition as recited in present claims 1-14 and one single alpha-2-delta ligand compound as recited in present claims 16-19 for prosecution on the merits to which the claims will be restricted if no generic claim is finally held to be allowable. Claims 1-14, 16 and 17-19 were identified as generic.

Applicant's election of the species of restless leg syndrome as the single disclosed species of disorder or condition as recited in present claims 1-14 and the election of pregabalin as the single disclosed species of alpha-2-delta ligand in the reply filed May 8, 2006 is acknowledged. Insofar as Applicant has failed to particularly point out the supposed errors in the requirement for election, Applicant's election has been herein treated as an election **without traverse**. Please reference MPEP §818.03(a).

Therefore, for the reasons above and those made of record at pages 2-5 of the previous Office Action dated March 7, 2006, the restriction requirement is deemed proper and is made **FINAL**.

Claims 1-11, 13-16 and 19 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected subject matter.

The claims corresponding to the elected subject matter are 12, 17-18 and 20 and such claims are herein acted on the merits.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claim 17 is drawn to an alpha-2-delta ligand wherein the ligand “is a compound of formula II and pharmaceutically acceptable salts thereof” (see lines 2-4 of present claim 17). It is unclear whether Applicant intends the alpha-2-delta ligand to be a compound of formula II **and** pharmaceutically acceptable salts thereof, or whether Applicant intends the alpha-2-delta ligand to be a compound of formula II **or** pharmaceutically acceptable salts thereof. In other words, the claim does not clearly delineate whether the pharmaceutically acceptable salts of the alpha-2-delta ligand are a required component of the claim or whether they are an optional formulation of the alpha-2-delta ligand compound of formula II.

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In light of such reasons, one of ordinary skill in the art would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection. The claims, therefore, fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are properly rejected.

*Claim Rejection - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brummel et al. (WO 01/01983; 2001).

Brummel et al. teaches a method for the treatment of pain in a mammal in need thereof (page 12, line 14; see present claim 12) comprising administering a therapeutically effective amount of pregabalin or a pharmaceutically acceptable salt or hydrate thereof (page 12, lines 17-18; see present claims 17-18 and 20) and a therapeutically effective amount of gabapentin or a pharmaceutically acceptable salt of hydrate thereof (page 12, lines 15-16) in unit dosage form (page 12, line 18) or via concomitant administration (page 12, line 20), wherein the pain is restless leg syndrome (page 6, line 23; see present claims 12 and 20).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference the review article to Walther ("Treating Restless Legs Syndrome: Current Pathophysiological Concepts and Clinical Trials", *Expert Opin. Investig. Drugs*, 2002), the review article to Fulda et al. ("Emerging Drugs for Restless Legs Syndrome", *Expert Opin. Investig. Drugs*, 2005), Adler ("Treatment of Restless Legs Syndrome with Gabapentin", *Clinical Neuropharmacology*, 1997) and Mellick et al. ["Management of Restless Legs Syndrome with Gabapentin (Neurontin®), *Sleep*, 1996).

Rejection of claims 12, 17-18 and 20 is deemed proper.

No claims of the present application are allowed.

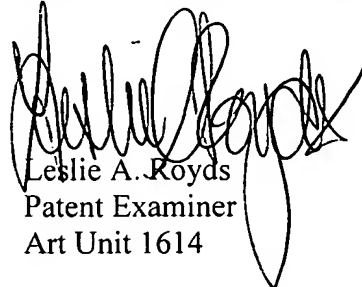
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

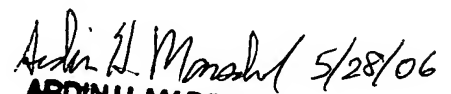
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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie A. Royds  
Patent Examiner  
Art Unit 1614

May 22, 2006



**ARDIN H. MARSCHEL**  
SUPERVISORY PATENT EXAMINER